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10.0 SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	USGI Medical, Inc. 1140 Calle Cordillera San Clemente, CA 92674
OFFICIAL CORRESPONDENT	Jeffrey A. Anderson Regulatory Consultant USGI Medical, Inc. 1140 Calle Cordillera San Clemente, CA 92674 Tel: (949) 633-5067 FAX (949) 369-3891 e-mail: Janderson@usgimedical.com

TRADE NAME:	USGI Shape Locking Endoscopic Overtube
COMMON NAME:	Overtube
CLASSIFICATION NAME:	Endoscope and accessories
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §876.1500
PRODUCT CODE	78 (KOG)
PREDICATE DEVICE:	USGI Shape Locking Endoscopic Overtube (K023902)

SUBSTANTIALLY EQUIVALENT TO:

USGI Shape Locking Endoscopic Overtube (cleared for market under K023902)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The USGI Shape Locking Endoscopic Overtube is an endoscopic accessory designed to provide external support to an endoscope without hindering its flexibility and maneuverability. It is an overtube guide that can conform to any bend configuration of the scope and then be shape locked in that form. In the "shape locked" configuration, the scope can be further advanced or withdrawn repeatedly.

INDICATION FOR USE:

The USGI Shape Locking Endoscopic Overtube is intended to be used with an endoscope to facilitate intubation, e.g., colonoscopy, change of endoscopes, removal of multiple polyps and/or foreign bodies.

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TECHNICAL CHARACTERISTICS:

The USGI Shape Locking Endoscopic Overtube is a shape locking tube with an atraumatic tip, a slip coated inner liner, a smooth outer skin, and a handle. The Shape Locking Tube is constructed from multiple nested links that are held together by four cables. Applying tension to the cables squeezes the links together. The friction between links maintains their relative positions, allowing the practitioner to "lock in" a shape.

PERFORMANCE DATA:

All components that come in direct contact with the patient have a long history of use in medical devices and are biocompatibile This 510(k) notice includes mechanical and functional bench testing that demonstrate that the USGI Shape Locking Endoscopic Overtube performs as intended.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The USGI Shape Locking Endoscopic Overtube is substantially equivalent to the previous version of the USGI Shape Locking Overtube (cleared for market under K023902). Both devices have the same indication for use and are made of the same materials (patient-contacting materials). Bench testing demonstrates that the devices are functionally equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

Mr. Jeff Anderson
Regulatory Consultant
USGI Medical, Inc.
1140 Calle Cordillera, Suite A & B
SAN CLEMENTE CA 92673

Re: K033954
Trade/Device Name: USGI Endoscopic Sheath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: December 19, 2003
Received: December 22, 2003

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K033954

Device Name: USGI Endoscopic Sheath

Indications for Use:

The USGI Shape Locking Endoscopic Overtube is intended to be used with an endoscope to facilitate intubation, e.g., colonoscopy, change of endoscopes, removal of multiple polyps and/or foreign bodies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lepurn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033954